REMARKS

Drawings

Please confirm that the amendments to the specification, and the previously submitted remarks, have overcome the previous objections to the drawings.

Rejections under 35 U.S.C. 112

Claims 58-60 and 62 were rejected under 35 U.S.C. 112, as indefinite. This rejection is respectfully traversed if applied to the amended claims. The claims have been amended for consistency and antecedent basis.

Double Patenting

Claims 43 and 58-62 were rejected for obviousness-type double patenting over claims 21, 25-30 and 47 of U.S. Patent No. 6,171,610. Solely to facilitate prosecution, a Terminal Disclaimer to U.S. Patent No. 6,171,610 will be submitted shortly.

Rejection under 35 U.S.C. 102

Claims 43 and 58-62 were rejected under 35 U.S.C. 102(e) as disclosed by U.S. Patent No. 5,776,747 to Schinstine ("Schinstine"). This rejection is respectfully traversed if applied to the amended claims.

The following is a quote from the specification, relating to the criteria for the support structure:

"The invention has many advantages. For example, upon gelling, the hydrogel-cell composition is supported by the support structure and forms a uniform suspension in which nutrients can readily diffuse to the cells and waste products can diffuse away from the cells. As a result, the hydrogel keeps the cells viable and allows vascularization of the suspension,

ultimately resulting in the growth of new tissue and its engraftment to the patient's body. The permeable support structure, into which the liquid hydrogel-cell composition is delivered, provides a shape and structure for the solidifying hydrogel-cell composition while still allowing nutrients and waste products to diffuse to and from the cells within the hydrogel. Thus, the *support structure guides the development and shape of the new tissue, and does so with the ability to resist external stresses from the environment and surrounding tissues*, i.e., the support structure is immediately weight-bearing, for example if the structure is used to replace a bone or cartilage. Moreover, the weight bearing characteristic of the support structure in bone or cartilage enables stresses to be transmitted across the hydrogel-cell suspension that will encourage bone or cartilage development in the hydrogel-cell suspension.

In the absence of such a support structure, a patient would not be able to apply any weight or stress to the hydrogel-cell composition because such forces would cause the hydrogel-cell composition to become distorted and displaced. This is similar with any replacement of structural tissues which are exposed to stress, such as ligaments, tendons, and bones anywhere within the body. Note also that the support structure accommodates not only compressive forces but also tensile forces, such as when one pulls on a tendon or stretches skin. In such cases, the support structure mimics the elasticity of the tendon or skin, and has ends that are typically sutured or adhered to adjacent tissue.

Composite support structures are also possible. For example, one can create a support structure that has a hollow tube of solid material, e.g., coral, on the outside loaded with a hydrogel-osteoblast (or other bone precursor cells) composition, and a softer support in the center such as a fiber mesh loaded with a hydrogel-spinal cord stem cell composition.

Also, the support structure maintains the structural integrity and the desired shape of the hydrogel-cell composition without altering the physical characteristics of the hydrogel-cell composition in ways that can harm the cells and limit the diffusion of nutrients and waste products to and from the cells.

Furthermore, the support structure can be designed to be compressible and resilient so that it can be easily implanted into a patient through, for example, a cannula, endoscope, or arthroscope. Thus, the support structure can be cut or molded into the shape of the desired tissue to be grown, implanted into the patient in a deformed state through a cannula, allowed to expand within the desired body cavity, and subsequently injected with the liquid hydrogel-cell composition. The subsequent growth of new tissue will take the shape of the support structure." (emphasis added to show basis for claim amendments)

The claims have been amended to incorporate these requirements of the support structure for providing support as well as guidance for formation of the cells. No where does Schinstine disclosure such a support structure - indeed, Schinstine teaches away from such a structure since Schinstine's goals are very different, that is not to form new tissue within the body but to provide metabolic supplementation or replacement. To the extent a support structure is incorporated, it is to promote attachment, proliferation and function of the cells, not to provide immediate weight bearing function and guide new tissue formation. See the following excerpts from Schinstine:

"As used herein, a "bioartificial organ" or "BAO" is a device which may be designed for implantation into a host or which may be made to function extracorporeally and either be permanently or removably attached to a host. A BAO contains cells or living tissues which produce a biologically active molecule that has a therapeutic effect on the host." See also "In

another embodiment, the interior of the BAO may be altered by providing an inert scaffold within the BAO prior to loading cells. This scaffold provides a structure for adhering and evenly distributing cells within the capsule. Compounds useful in the preparation of an inert scaffold include, poly(hydroxyethyl methacrylate)("PHEMA") and poly(hydroxyethyl methacrylate-co-methyl methacrylate) ("PHEMA/MMA"). Furthermore, the scaffold may be derivatized with various chemicals or proteins, including those discussed supra, to further control growth and differentiation. According to this method, solutions of a suitable scaffold material are precipitated in the BAO for the desired scaffold.

Another embodiment contemplates culturing cells on a member which will serve as an internal support. The internal support may be made of any substantially biocompatible material such as titanium or a suitable polymer. The support can be in the form of a strut or may be designed to also function as a scaffold, by providing a large amount of surface area for cell growth. One example of such a scaffold material is a non-woven polyester fabric (NWPF) (Reemay, Tenn.). There are numerous types of NWPF, varying in tightness of weave and thickness of the sheet. Such technique allows precise control over number of cells in a BAO, as well as the ability to qualify the cells/scaffold prior to insertion in the BAO. Further, differentiation of cells cultured on such a material (external to the device) could be accomplished prior to insertion of the material into the device."

The Examiner's suggestions with respect to the method of dissociating the cells are greatly appreciated. However, a major aspect of this invention, and what is being used in the clinical trials, are cells that are merely isolated by digestion of tissue, then implanted into the

spinal cord or bone for regeneration and repair of these structures. It is the support structure as much as the cells that is critical to the success of these devices.

Allowance of claims 43, 44 and 54-62 as amended is earnestly solicited.

Respectfully submitted,

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